

Fax Cover Sheet

Lilly

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

LRL Law

To: Anish Gupta

From: Greg Cox

Company: USPTO

Fax: (317) 276-5172

Fax: 703-746-4986

Phone: 317 277-2620

Phone: 703-308-4001

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Answers That Matter.

To: Anish Gupta

From: Greg Cox

Date: August 26, 2003

Re: Personal Interview Agenda for case US 09/400,802

Atty Docket X-11158

I. Introduction:

- a. This is a very important case to Eli Lilly and Company. Lilly is expanding its critical care focus following the recent success of Xigris for the treatment of Sepsis.

II. Procedural History:

- a. This case claims priority to provisional application US 60/10179, filed September 24, 1998. The case was issued a restriction requirement in December 2000, and Applicants responded in March 2001. The case was not issued a first substantive office action until June 2003, and Applicants response is due September 4, 2003.

III. Discussion of reports in the literature suggesting no correlation between hyperglycemia and poor prognosis after suffering a stroke.

- i. Tracey et al. Hyperglycaemia and mortality from acute stroke. *Q. J. Med.* 1993; 86:439-446.
- ii. Woo et al. The Influence of Hyperglycemia and Diabetes Mellitus on Immediate and 3-Month Morbidity and Mortality After Acute Stroke. *Arch Neurol.* 1990; 47:1174-77.
- iii. Zasslow et al. Hyperglycemia Decreases Acute Neuronal Ischemic Changes After Middle Cerebral Artery Occlusion in Cats. *Stroke* 1989; 20:519-523.

IV. Discussion of the 103 Rejection based on the Dietrich reference.

V. Discussion of data generated using an animal model for studying cerebral ischemia.

VI. Discussion of issued US patents claiming related subject matter.

- a. US 6,429,197 Metabolic Intervention with GLP-1 or its Biologically Active Analogues to Improve the Function of the Ischemic and Reperfused Brain. Filed Apr. 30, 1999.
 - i. Continuation-in-part of provisional application No. 60/103,498 filed on Oct. 8, 1998.
- b. US 6,284,725 Metabolic Intervention with GLP-1 to Improve the Function of the Ischemic and Reperfused Tissue.
 - i. Continuation-in-part of provisional application No. 60/103,498 filed on Oct. 8, 1998.
- VII. Discussion of amendments to the claims and additional claims to be submitted with the response due September 4, 2003.